

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

FILED

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CLERK OF DISTRICT COURT
WESTERN DISTRICT OF TEXAS

BY _____

EDITH MEREDITH,

Plaintiff,

-vs-

Case No. A-13-CA-208-SS

NUVASIVE, INC.,

Defendant.

ORDER

BE IT REMEMBERED on the 6th day of December, 2013, the Court called a hearing in the above-styled cause, and the parties appeared by and through counsel. Before the Court are Plaintiff Edith Meredith's Motion for Partial Summary Judgment [#34], Defendant NuVasive, Inc.'s Response [#35], and Meredith's Reply [#38]; and Meredith's "Motion for Leave to Exceed Rule 30 Presumptive Deposition Limit and Motion to Compel" [#45], NuVasive's Response [#47], and Meredith's Reply [#48]. Having reviewed the documents, the governing law, the arguments of counsel at the hearing, and the file as a whole, the Court now enters the following opinion and orders.

Background

In this products liability case, Meredith alleges NuVasive's "NVM5" neuromonitoring device malfunctioned during her spinal surgery, resulting in severe neurological damage and impairing her ability to use her left leg. Meredith's live pleading, filed after the pending summary judgment motion, alleges five causes of action: (1) products liability for a manufacturing defect; (2) breach of implied warranties; (3) negligence; (4) gross negligence; and (5) *res ipsa loquitur*. NuVasive's live

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answer, filed after its response to the pending summary judgment motion, alleges fifteen affirmative defenses (down from twenty-one in its previous answer). NuVasive now seeks summary judgment on several of those affirmative defenses.

Analysis

I. Motion for Partial Summary Judgment

A. Legal Standard

Summary judgment shall be rendered when the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine dispute as to any material fact and that the moving party is entitled to judgment as a matter of law. FED. R. CIV. P. 56(a); *Celotex Corp. v. Catrett*, 477 U.S. 317, 323–25 (1986); *Washburn v. Harvey*, 504 F.3d 505, 508 (5th Cir. 2007). A dispute regarding a material fact is “genuine” if the evidence is such that a reasonable jury could return a verdict in favor of the nonmoving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). When ruling on a motion for summary judgment, the court is required to view all inferences drawn from the factual record in the light most favorable to the nonmoving party. *Matsushita Elec. Indus. Co. v. Zenith Radio*, 475 U.S. 574, 587 (1986); *Washburn*, 504 F.3d at 508. Further, a court “may not make credibility determinations or weigh the evidence” in ruling on a motion for summary judgment. *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 150 (2000); *Anderson*, 477 U.S. at 254–55.

Once the moving party has made an initial showing that there is no evidence to support the nonmoving party’s case, the party opposing the motion must come forward with competent summary judgment evidence of the existence of a genuine fact issue. *Matsushita*, 475 U.S. at 586. Mere conclusory allegations are not competent summary judgment evidence, and thus are insufficient to

defeat a motion for summary judgment. *Turner v. Baylor Richardson Med. Ctr.*, 476 F.3d 337, 343 (5th Cir. 2007). Unsubstantiated assertions, improbable inferences, and unsupported speculation are not competent summary judgment evidence. *Id.* The party opposing summary judgment is required to identify specific evidence in the record and to articulate the precise manner in which that evidence supports his claim. *Adams v. Travelers Indem. Co. of Conn.*, 465 F.3d 156, 164 (5th Cir. 2006). Rule 56 does not impose a duty on the court to “sift through the record in search of evidence” to support the nonmovant’s opposition to the motion for summary judgment. *Id.* “Only disputes over facts that might affect the outcome of the suit under the governing laws will properly preclude the entry of summary judgment.” *Anderson*, 477 U.S. at 248. Disputed fact issues that are “irrelevant and unnecessary” will not be considered by a court in ruling on a summary judgment motion. *Id.* If the nonmoving party fails to make a showing sufficient to establish the existence of an element essential to its case and on which it will bear the burden of proof at trial, summary judgment must be granted. *Celotex*, 477 U.S. at 322–23.

B. Application

Meredith’s motion seeks summary judgment on roughly eight affirmative defenses, grouped as follows: (1) preemption; (2) the Texas Medical Liability Act; (3) lack of warranties; (4) “learned intermediary” and “risk/benefit comparison” defenses; and (5) various third party liability defenses. Since the filing of the motion and response, however, Meredith’s amended complaint and NuVasive’s amended answer appear to have removed the preemption, learned intermediary, and risk/benefit comparison defenses from the case. The Court therefore DISMISSES Meredith’s motion as to those claims, and turns to the arguments directed at currently pleaded defenses.

1. Texas Medical Liability Act

Meredith seeks summary judgment on NuVasive's Texas Medical Liability Act defense. The relevant statute does not technically provide NuVasive with any affirmative defense, but, if applicable, imposes caps on damages. *E.g.*, TEX. CIV. PRAC. & REM. CODE § 74.301 (\$250,000 cap on noneconomic damages). The statute applies by its terms to "health care liability claims," which are specifically defined as causes of action

against a health care provider or physician for treatment, lack of treatment, or other claimed departure from accepted standards of medical care, or health care, or safety or professional or administrative services directly related to health care, which proximately results in injury to or death of a claimant, whether the claimant's claim or cause of action sounds in tort or contract.

Id. § 74.001(13). The Texas Supreme Court has extracted "three basic elements" from this definition:

- (1) a physician or health care provider must be a defendant;
- (2) the claim or claims at issue must concern treatment, lack of treatment, or a departure from accepted standards of medical care, or health care, or safety or professional or administrative services directly related to health care; and
- (3) the defendant's act or omission complained of must proximately cause the injury to the claimant.

Tex. W. Oaks Hosp., LP v. Williams, 371 S.W.3d 171, 179–80 (Tex. 2012).

First, Meredith seeks summary judgment on the applicability of the TMLA because NuVasive does not qualify as a "health care provider." NuVasive naturally disagrees, arguing it is covered by at least one part of the sprawling definition of that term. Second, Meredith argues her products liability claims—even if brought alongside negligence theories—allege negligence in manufacturing a product, not negligence in providing health care, and thus do not satisfy the second

element of a health care liability claim. NuVasive counters Meredith's claims allege "a departure from accepted standards of . . . safety" and are therefore within the scope of the TMLA.

Meredith's first argument requires a deeper dive into the statutory definition of "health care provider." The term "health care provider" is defined as:

any person, partnership, professional association, corporation, facility, or institution duly licensed, certified, registered, or chartered by the State of Texas to provide health care, including:

- (i) a registered nurse;
- (ii) a dentist;
- (iii) a podiatrist;
- (iv) a pharmacist;
- (v) a chiropractor;
- (vi) an optometrist;
- (vii) a health care institution; or
- (viii) a health care collaborative certified under Chapter 848, Insurance Code.

Id. § 74.001(12)(A). The term also includes:

- (i) an officer, director, shareholder, member, partner, manager, owner, or affiliate of a health care provider or physician; and
- (ii) an employee, independent contractor, or agent of a health care provider or physician acting in the course and scope of the employment or contractual relationship.

Id. § 74.001(12)(B).

Meredith asserts NuVasive is a device manufacturer, not a health care provider. Although NuVasive concedes it does not fit within any of the listed categories in Section 74.001(12)(A), it contends it is a health care provider under Section 74.001(12)(B). NuVasive's specific theories include: (1) NuVasive's employee Jay Pendleton, who was present for Meredith's surgery, qualifies as an independent contractor of the hospital where the surgery was performed; (2) NuVasive

additionally qualifies as an “affiliate” of Pendleton, an independent contractor and therefore a health care provider himself; and (3) NuVasive is an affiliate of the hospital.

With respect to NuVasive’s first argument, the Court disagrees Pendleton was an independent contractor of the hospital. The sole basis for this claim is Pendleton’s signature on a hospital access policy, which required Pendleton, as a “Health Care Industry Representative,” to possess certain credentials and follow various hospital rules (e.g., drug testing, scheduling appointments in advance, following the hospital parking policy, sterilizing equipment before use). Def.’s Sealed Exs. [#36-2], Ex. E. The policy certainly requires Pendleton to follow certain rules to maintain his access to the hospital facilities, but says nothing about creating any sort of contractual relationship. The agreement is not even signed by the hospital; it is a unilateral promise by the outside vendor to follow hospital rules while in the hospital. Hospitals can control access to their facilities without forming independent contractor relationships with everyone who sets foot in the building. Pendleton’s status as a “Health Care Industry Representative” is considerably different from the traditional hospital–physician relationship, in which hospitals grant staff privileges to non-employee doctors. *See Berel v. HCA Health Servs. of Tex., Inc.*, 881 S.W.2d 21, 23 (Tex. App.—Houston [1st Dist.] 1994, writ denied) (discussing the employee/independent contractor distinction in the context of *respondeat superior* liability of hospitals for negligence of doctors). Pendleton was a NuVasive employee who happened to need certain credentials to access the hospital. The hospital’s willingness to provide access to Pendleton subject to certain conditions does not fundamentally alter the relationship of the parties.

Second, because the Court finds Pendleton was not an independent contractor of the hospital, NuVasive cannot piggyback its way into health care provider status using Pendleton. *See* TEX. CIV. PRAC. & REM. CODE § 74.001(12)(B)(i).

Third, and similarly, the Court disagrees NuVasive is an “affiliate” of the hospital. The TMLA defines an “affiliate” as “a person who, directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with a specified person, including any direct or indirect parent or subsidiary.” *Id.* § 74.001(a)(1). As NuVasive suggests, the key to this definition is the notion of control. The hospital in this case does not control NuVasive in any meaningful sense. It allows doctors to use NuVasive products if they wish. It also requires NuVasive employees to follow hospital rules while in the hospital. If NuVasive’s argument is correct, the TMLA’s definition of affiliate would make virtually every product manufacturer with a product located anywhere in a hospital—from chairs to tongue depressors to urinals—an affiliate, and therefore a health care provider. The term “control” as used in the TMLA must mean something more.

Alternatively, even if NuVasive is a health care provider, Meredith’s products liability claims are not the type of claims encompassed by the TMLA. *See In re Temple*, 239 S.W.3d 885, 889 (Tex. App.—Texarkana 2007, no pet.) (“Claims regarding products liability or negligent manufacture—even when those items are medical devices—are not expressly or impliedly covered by Chapter 74.”). Other Texas statutes define “products liability actions” as actions “against a manufacturer or seller for recovery of damages or other relief for harm allegedly caused by a defective product, whether the action is based in strict tort liability, strict products liability, negligence, misrepresentation, breach of express or implied warranty, or any other theory or

combination of theories.” TEX. CIV. PRAC. & REM. CODE § 16.012(a)(2). The Texas legislature has thus distinguished between health care liability and products liability claims, even when negligence theories are involved.

Although Meredith does allege negligence causes of action, the alleged negligence is a breach of NuVasive’s duty of ordinary care by, for example, failing to remove the NVM5 device from the market after previous known failures, and failure to adequately test the NVM5 device before allowing its use. 3d Am. Compl. [#37] ¶¶ 5.14–.15. Meredith did not sue the doctor or the hospital for breaching some duty of care regarding her surgery. Instead, she sued the company which manufactured an allegedly faulty product. This Court does not read the TMLA so expansively as to encroach on products liability law in all cases involving medical devices.¹

Accordingly, the Court GRANTS Meredith’s motion for summary judgment on NuVasive’s invocation of the TMLA’s damages caps (and any other relevant provisions).

2. Lack of Warranties Defense

Meredith seeks summary judgment on NuVasive’s lack of warranties defense. NuVasive argues the Uniform Commercial Code’s warranty provisions are inapplicable to the allegedly malfunctioning product here, the NVM5 “patient module,” because NuVasive has not provided any implied warranties of merchantability or fitness for a particular purpose.

Pursuant to the UCC, certain warranties may be implied when a product is sold or leased. *See* TEX. BUS. & COM. CODE § 2.314 (implied warranty of merchantability in sale); *id.* § 2.315 (implied

¹ The Court reaches this conclusion with full knowledge of how expansively the Texas Supreme Court has read the TMLA in the past. *See, e.g., St. David’s Healthcare P’ship, L.P., LLP v. Esparza*, 348 S.W.3d 904, 906 (Tex. 2011) (holding hospital patient who sued for injuries sustained after he slipped on lubricating gel spilled on the floor had asserted a health care liability claim); *Omaha Healthcare Center, LLC v. Johnson*, 344 S.W.3d 392, 395 (Tex. 2011) (suit over fatal brown recluse spider bite in nursing home was a health care liability claim).

warranty of fitness for a particular purpose in sale); *id.* § 2A.212 (implied warranty of merchantability in lease); *id.* § 2A.213 (implied warranty of fitness for a particular purpose in lease). A “sale” is defined as “the passing of title from the seller to the buyer for a price.” *Id.* § 2.106(a). A “lease” is defined as “a transfer of the right to possession and use of goods for a term in return for consideration.” *Id.* § 2A.103(a)(10).

NuVasive contends there was neither a sale nor a lease of the NVM5 patient module in this case. Pendleton testified NuVasive charges for various “disposables,” single-use components used in the relevant procedures, but does not charge for the NVM5 patient module Meredith alleges malfunctioned. Def.’s Sealed Exs. [#36-1], Ex. B (Pendleton Depo), at 17–18. Additionally, neither the hospital, Dr. Rumi, or Meredith were charged for the use of any disposables or the NVM5 patient module used in Meredith’s surgery. *Id.* at 22. Because the only product Meredith alleges malfunctioned was not sold or leased to the hospital, to the surgeon, or to Meredith, NuVasive argues no warranties were implied.

Meredith focuses on the Texas Supreme Court’s refusal to impose a strict privity of contract requirement in breach of warranty cases. *See Garcia v. Tex. Instruments, Inc.*, 610 S.W.2d 456, 465 (Tex. 1980) (holding “privity of contract is not a requirement for a Uniform Commercial Code implied warranty action for personal injuries”). But *Garcia*, and the more recent federal cases Meredith cites applying *Garcia*, still involved an actual sale of a product to someone, even if the buyer was not the plaintiff. *See id.* at 457 (sulfuric acid sold by defendant to plaintiff’s employer); *Oldham v. Thompson/Center Arms Co.*, No. H-12-2432, 2013 WL 4042010, at *1 (S.D. Tex. Aug. 8, 2013) (rifle sold to plaintiff by defendant); *Ackermann v. Wyeth Pharms.*, 471 F. Supp. 2d 739,

744 (E.D. Tex. 2006) (“Bottom line, under strict statutory interpretation, there must be an underlying sale to trigger the applicability of the [UCC].”).

Meredith has not presented any evidence the NVM5 patient module was sold to the hospital, to the doctor, to her, or to anyone else. Nor has Meredith presented any evidence the NVM5 patient module was leased to anyone in exchange for consideration. The fact NuVasive ultimately sought to profit off using the NVM5 device in the hospital by charging for disposables used in specific procedures does not establish either the hospital or the surgeon had leased the device from NuVasive. *See* TEX. BUS. & COM. CODE § 2A.103(a)(10). NuVasive has presented evidence the NVM5 patient module was not sold or leased to anyone. Based on this record, the Court cannot say Meredith is entitled to summary judgment on NuVasive’s lack of warranties defense. Meredith’s motion is DENIED on this ground.²

3. Third Party Liability Defenses

Meredith seeks summary judgment on various defenses alleging unidentified third parties are responsible for some or all of Meredith’s injuries. The most likely target seems to be Dr. Rumi, the doctor who performed Meredith’s surgery. However, NuVasive has yet designated any particular third party as responsible, and discovery is still ongoing. The Court will therefore DISMISS Meredith’s motion on these grounds without prejudice to raising the issue if and when NuVasive designates any specific third party or parties.

² As expressed at the hearing, this is a products liability and negligence case, not a warranties case. Given the limited time counsel will ultimately have at trial, both sides would benefit from narrowing the issues to the core disputes the parties intend to present to the jury.

II. Motion for Additional Depositions

Meredith seeks to depose up to four additional fact witnesses: (1) Phillip Palmer, a NuVasive employee allegedly involved with the distribution of the device used in Meredith's surgery to Austin from Memphis, Tennessee; (2) Joshua Griffin, a NuVasive employee who allegedly made a comment about the NuVasive device used in Meredith's surgery being broken; (3) Steve Birnbaum, a NuVasive representative allegedly involved in an earlier procedure involving the device used in Meredith's surgery in Seattle, Washington; and (4) an unidentified doctor who performed a procedure using the device in Seattle. These witnesses may provide testimony relevant to Meredith's case or NuVasive's defenses, and Meredith is entitled to depose them. The Court will GRANT the motion and allow depositions, with each deposition not to exceed four hours in length. With respect to the unidentified doctor, the Court trusts the parties will work together to determine if such an individual exists (particularly in light of Mr. Birnbaum's testimony), and, if so, identify the individual and arrange the deposition.

Conclusion

Accordingly,

IT IS ORDERED that Plaintiff Edith Meredith's Motion for Partial Summary Judgment [#34] is GRANTED IN PART, DENIED IN PART, and DISMISSED IN PART, as described in this opinion;

IT IS FINALLY ORDERED that Meredith's "Motion for Leave to Exceed Rule 30 Presumptive Deposition Limit and Motion to Compel" [#45] is GRANTED, subject to the conditions described in this opinion.

SIGNED this the 9th day of December 2013.



SAM SPARKS
UNITED STATES DISTRICT JUDGE